



UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST INVENTOR
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09/941,882 08/28/2001

21003 7590 07/23/2003

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NOTE: IF PERIOD OF
REPLY SET TO
EXPIRE 3 MONTH
IT'S NON-FINAL
(2) 1 MONTH
CTRS

- JUST REMINDER -

COMMERCE
& Office

FORMATION NO.

9563

PER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,882

Applicant(s)

WILLIAMS ET AL.

Examiner

Jezia Riley

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12, 16, 17, 21, 22 and 27 is/are rejected.
- 7) ☒ Claim(s) 4-11, 13-15, 18-20, 23-26 and 28-30 is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I in Paper No. 7 is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities: The continuation data of the present application are not present in the specification first paragraph. Appropriate correction is required.

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0223618.

The reference discloses a process for nucleotide sequencing of DNA or RNA that does not require for radioactivity or gel electrophoresis. The method includes a primed single-stranded nucleotide template and polymerase. The reaction conditions are

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adjusted to allow incorporation. The reaction mixture is washed so that unincorporated precursors are removed while the primed template and polymerase are retained in the reaction mixture. The method is readily automatic. The reaction chamber may be attached to five reservoirs, and have an outlet which feeds the effluent into the detection instrument used for the assay(see col. 6-9 and 12-13). The preferred polymerase is a polymerase that is low in the 5'to 3' exonuclease (col. 12, lines 43-45).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-3, 12, 16, 17, 21, 22, 27 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over EP 0223618 in view of Tsien et al. (WO 91/06678) in view of Hyman et al. (WO 89/09283) and in further view of Barnes (5,436,149).

EP 0223618 discloses a process for nucleotide sequencing of DNA or RNA that does not require for radioactivity or gel electrophoresis. The method includes a primed single-stranded nucleotide template and polymerase. The reaction conditions are adjusted to allow incorporation. The reaction mixture is washed so that unincorporated precursors are removed while the primed template and polymerase are retained in the reaction mixture. The method is readily automatic. The reaction chamber may be attached to five reservoirs, and have an outlet which feeds the effluent into the detection instrument used for the assay(see col. 6-9 and 12-13). The preferred polymerase is a polymerase that is low in the 5'to 3' exonuclease (col. 12, lines 43-45).

Tsien et al. discloses a method and apparatus to determine the nucleotide sequence in DNA molecule (pages 6-15). The incorporation of each dNTP is noted by detecting a label or reporter group or fluorescent tag. Label can be attached to the dNTP through a spacer which can be cleavable if desired to release the fluorophore or other label on demand (page 7).

Hyman et al. discloses a pyrophosphate-based method and apparatus for sequencing nucleic acid. The invention utilizes ATP-sulfurylase and an ATP-dependent luciferase to analyze the recovered feedstocks for inorganic pyrophosphate.

It would have been obvious at the time the invention was made to utilize fluorescent label as taught by Tsien for the method of EP 0223618. The motivation is in many cases particularly with fluorescent labels, increased detection sensitivity is a major advantage (Tsien et al, page 31). Further, the approach of using the measurement of Ppi as taught by Hyman et al. provides a simple method for rapid

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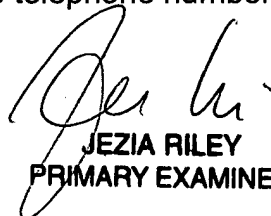
determination of nucleic acid sequences (Hyman page 2). Additionally a formulation comprising a mixture of at least one polymerase lacking 3'-exonuclease activity and at least one polymerase exhibiting 3'-exonuclease activity can be created and used to catalyze primer extension during PCR process, thus extending the applicable size range for efficient PCR amplification (Barnes col. 3-4).

7. Claims 4-11, 13-15, 18-20, 23-26, 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


JEZIA RILEY
PRIMARY EXAMINER

July 15, 2003